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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,247

07/09/2003

Philip S. Kim

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9491

64574

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04/29/2008

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PHILADELPHIA, PA 19103

EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

04/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,247	Applicant(s) KIM, PHILIP S.	
	Examiner THEODORE J. STIGELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 30-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 30-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/5/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-4, 14-15, 20-21, 30-33, and 36-37 are rejected under 35

U.S.C. 102(b) as being anticipated by Ellinwood Jr. (3,923,060). Ellinwood discloses a method of providing long term pain management comprising the steps of surgically implanting a catheter (248) to create an infusion site, wherein a discharge portion of the catheter lies in a peripheral neural structure, surgically implanting an implantable pump (150 or Figure 13) and a reservoir (126 or Figure 13) in subcutaneous tissue, wherein the proximal end of the catheter and the reservoir are in communication with the pump, and operating the pump to deliver a predetermined dosage of medication through the discharge portion of the catheter into the infusion site whereby pain management is provided for weeks, months, or years, wherein the catheter is lined with a metal strip (251) conductive to electricity. Ellinwood's disclosure from column 6, line 15- column 8, line 9 discloses multiple examples of implanting a catheter in peripheral neural

structures and column 7, lines 15-22 indicates that pain management is one of the applications Ellinwood contemplated.

Claims 1, 3-4, 14-15, 20-21, 30-33, and 36-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Gelfand et al. (US 2005/0192638). Gelfand discloses a method of providing long term pain management comprising the steps of surgically implanting a catheter (106) to create an infusion site, wherein a discharge portion of the catheter lies in a peripheral neural structure, surgically implanting an implantable pump (105) and a reservoir (403) in subcutaneous tissue, wherein the proximal end of the catheter and the reservoir are in communication with the pump, and operating the pump to deliver a predetermined dosage of medication through the discharge portion of the catheter into the infusion site whereby pain management is provided for weeks, months, or years, wherein the catheter is lined with a metal strip (413) conductive to electricity. Gelfand discloses using an implantable pump and catheter to discharge local anesthetic to the renal nerve in provisional application 60/370,190 (see page 22 and disclosure for Figure 4). The examiner contends that local anesthetic is a pain killer and/or reducer.

Claims 1, 3-4, 14-15, 20-21, 30-33, and 36-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Mann et al. (6,941,171). Mann discloses a method of providing long term pain management comprising the steps of surgically implanting a catheter (80) to create an infusion site, wherein a discharge portion of the catheter lies in a peripheral neural structure (at least pudendal and sacral nerve stimulation are contemplated), surgically implanting an implantable pump (100) and a

reservoir (inside of 100) in subcutaneous tissue, wherein the proximal end of the catheter and the reservoir are in communication with the pump, and operating the pump to deliver a predetermined dosage of medication through the discharge portion of the catheter into the infusion site whereby pain management is provided for weeks, months, or years, wherein the catheter is lined with a metal strip (72) conductive to electricity.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 5-13, 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood Jr. (3,923,060) or Mann et al. (6,941,171). Ellinwood and Mann disclose methods of pain management including all of the limitations recited in the independent claims but fail to specifically teach implanting the catheter in the nerves recited in the claims above. The examiner maintains, however, that these limitations are matters of design choice as the applicant has not shown that specifically implanting to any of these

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sites works better than any other site. In fact, the applicant seems to concede that the novelty of the invention is the implantation to any peripheral nerve rather than to the recited nerves (see paragraph [0060] of applicant's specification). One skilled in the art would recognize that Ellinwood's and Mann's disclosure would apply to any peripheral nerve structure.

Claims 16 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood Jr. (3,923,060) or Mann et al. (6,941,171) in view of Klein et al. (Anesth Analg 2000; 91:1473-1478). Ellinwood and Mann disclose all of the limitations recited in the independent claim but fail to teach using local anesthetics for pain relief. The study by Klein shows that local anesthetics are good pain killers when used in the peripheral nerves. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify to method of Ellinwood or Mann with the use of local anesthetics because it is known in the art that local anesthetics are a reliable choice for pain relief in peripheral nerves.

Claims 17, 35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann et al. (6,941,171) in view of Gerber et al. (6,360,750). Mann discloses all of the limitations recited in the independent claim but fails to teach using antispasmodics. Gerber teaches that using antispasmodics is well-known in the art in helping bladder control. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify to method of Mann with the use of antispasmodics to provide a better treatment of incontinence and pain relief.

Response to Arguments

Applicant's arguments filed 12/5/2007 have been fully considered but they are not persuasive. The examiner maintains that Ellinwood and Gelfand teach pain management and has pointed to more specific teachings in the disclosures.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763